

YOUNG CONAWAY STARGATT & TAYLOR, LLP

BEN T. CASTLE
SHELDON N. SANDLER
RICHARD A. LEVINE
RICHARD A. ZAPPA
FREDERICK W. IOBST
RICHARD H. MORSE
DAVID C. MCBRIDE
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CRAIG A. KARSNITZ
BARRY M. WILLOUGHBY
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JOHN T. DORSEY
M. BLAKE CLEARY
CHRISTIAN DOUGLAS WRIGHT
DANIELLE GIBBS
JOHN J. PASCHETTO
NORMAN M. POWELL

THE BRANDYWINE BUILDING
1000 WEST STREET, 17TH FLOOR
WILMINGTON, DELAWARE 19801

P.O. Box 391
WILMINGTON, DELAWARE 19899-0391

(302) 571-6600
(800) 253-2234 (DE ONLY)
FAX: (302) 571-1253

110 WEST PINE STREET
P.O. Box 594
GEORGETOWN, DELAWARE 19947

(302) 856-3571
(800) 255-2234 (DE ONLY)
FAX: (302) 856-9338

WWW.YOUNGCONAWAY.COM

DIRECT DIAL: (302) 571-6554
DIRECT FAX: (302) 576-3467
kkeller@ycst.com

LISA A. ARMSTRONG
GREGORY J. BABCOCK
JOSEPH M. BARRY
SEAN M. BEACH
DONALD J. BOWMAN, JR.
TIMOTHY P. CAIRNS
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RICHARD S. JULIE
KAREN E. KELLER
JENNIFER M. KINKUS
EDWARD J. KOSMOWSKI
JOHN C. KUFFEL

SPECIAL COUNSEL
JOHN D. MCCLAUGHLIN, JR.
ELENA C. NORMAN
KAREN L. PASCALE
PATRICIA A. WIDDOSS

KAREN LANTZ
TIMOTHY E. LENGKEEK
ANDREW A. LUNDGREN
MATTHEW B. LUNN
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MICHAEL P. STAFFORD
CHAD S.C. STOVER (SC ONLY)
JOHN E. TRACEY
MARGARET B. WHITEMAN
SHARON M. ZIEG

SENIOR COUNSEL
CURTIS J. CROWTHER

OF COUNSEL
BRUCE M. STARGATT
STUART B. YOUNG
EDWARD B. MAXWELL, 2ND

July 7, 2006

BY CM/ECF AND HAND DELIVERY

The Honorable Gregory M. Sleet
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, Delaware 19801

Re: *Aventis Pharmaceuticals, Inc., et al. v. Barr Laboratories, Inc.,*
C.A. No. 06-286 (GMS)

Dear Judge Sleet:

We represent Defendant Barr Laboratories, Inc. in the captioned matter. We write pursuant to L.R. 7.1.2(c), to call to the Court's attention a subsequent decision relevant to Barr's pending motion to dismiss or bifurcate Plaintiffs' willful infringement claims.

On July 6, 2006, Judge Kent Jordan of this District issued an order striking a patentee's willful infringement claims against an ANDA applicant. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, C.A. No. 05-700-KAJ, Mem. Order at 5-6 (D. Del. July 6, 2006) (Ex. A, attached hereto). The court determined that "[t]he more recent and growing weight of authority . . . seems to be that an ANDA filing and accompanying paragraph IV certification cannot support a charge of willful infringement." (*Id.* at 4). The court found that authority "persuasive" and, accordingly, granted the motion to strike. The court also stayed all discovery on whether the case is exceptional under 35 U.S.C. § 285.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

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Please do not hesitate to contact us if you have any questions on this matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Karen E. Keller". The signature is fluid and cursive, with the first name "Karen" being more prominent than the last name "Keller".

Karen E. Keller (#4489)

Enclosure

cc: Steven J. Balick, Esq. (by CM/ECF and hand delivery)
John G. Day, Esq. (by CM/ECF and hand delivery)
Tiffany Geyer Lydon, Esq. (by CM/ECF and hand delivery)
Paul H. Berghoff, Esq. (by electronic mail)
Joshua R. Rich, Esq. (by electronic mail)
Jeremy Noe, Esq. (by electronic mail)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM)	
INTERNATIONAL GMBH and)	
BOEHRINGER INGELHEIM)	
PHARMACEUTICAL, INC.,)	
)	
Plaintiffs and)	
Counterclaim Defendants,)	
)	Civil Action No. 05-700-KAJ
v.)	(Consolidated)
)	
BARR LABORATORIES, INC., et al.)	
)	
Defendants and)	
Counterclaim Plaintiffs.)	

MEMORANDUM ORDER

Introduction

Before me is a Motion for Reconsideration (Docket Item ["D.I."] 39; the "Motion")¹ filed by defendant Mylan Pharmaceuticals Inc. ("Mylan") with respect to my previous ruling denying without prejudice Mylan's Motion to Strike Plaintiffs' Allegations Concerning Willful Infringement and to Bar All Discovery Relating Thereto (D.I. 8 in 05-854-KAJ; the "Motion to Strike"). For the reasons that follow, the Motion is treated as a renewal of the Motion to Strike, in which co-defendants Barr Laboratories, Inc. and Barr Pharmaceuticals Inc. (collectively "Barr") are deemed to join (see D.I. 55 at n. 1 ("Should the Court grant Mylan's motion, Barr will renew without delay its motion to

¹By order dated January 31, 2006, Civil Actions 05-700-KAJ and 05-854-KAJ were consolidated. (D.I. 33 in 05-700-KAJ.) Unless otherwise noted, citations to docket entries are to the docket in Civil Action No. 05-700-KAJ.

strike Boehringer's willfulness allegations.")), and is hereby granted to the extent described herein.

Background

This is a patent infringement case in which the plaintiffs, Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceutical Inc. (collectively "Boehringer"), assert that Mylan and Barr have infringed certain United States Patents owned by Boehringer. (See D.I. 1 at ¶¶ 18, 23.)² More specifically, Boehringer alleges that Barr has infringed Boehringer's U.S. Patents No. 4,886,812 (the "'812 patent") and No. 4,843,086 (the "'086 patent") by filing abbreviated new drug applications ("ANDAs") with the FDA, in an effort to market generic versions of drugs covered by those Boehringer patents. (*Id.* at ¶¶ 11-16, 18, 23.) Boehringer alleges essentially the same thing against Mylan with respect to the '812 patent. (D.I. 1 in 05-854-KAJ.) According to Boehringer, the defendants' infringement is willful (*id.* at ¶¶ 20, 25), and Boehringer therefore seeks, among other things, a declaration that this is an exceptional case warranting the imposition of Boehringer's attorneys' fees on the defendants. (*Id.* at *ad damnum* ¶¶ B. and E.) Both Mylan and Barr sought to strike the allegations of willfulness. (D.I. 9; D.I. 8 in 05-854-KAJ.) I denied those motions on January 27, 2006.

Standard of Review

"Motions for reconsideration are to correct manifest errors of law or fact or to present newly discovered evidence." *Pell v. E.I. DuPont De Nemours & Co., Inc.*, 231

²The allegations recited herein are effectively the same in the Amended Complaint filed against Barr. (See D.I. 7.)

F.R.D. 186, 188 (D.Del. 2005). The party seeking reconsideration must show "at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion ...; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir.1999).

Mylan has shown none of the applicable foundations for the granting of a motion for reconsideration. However, when I denied Mylan's Motion to Strike in the first instance, I expressly stated that the denial was "without prejudice" (1/27/06 Tr. at 11; see also D.I. 32),³ since I viewed the motions as "premature because I don't know what besides the filing of an ANDA might be in the mix here." (1/27/06 Tr. at 11.) The submissions of the parties have made it sufficiently clear to me that no other basis exists for the assertion of willfulness besides the defendants' filing of ANDAs and so I will accept the Motion as a renewed motion to strike on behalf of all of the defendants, which was expressly contemplated by my earlier ruling, rather than as a motion to reconsider the first denial.

Discussion

Since the decision by the United States Court of Appeals for the Federal Circuit in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), defendants in patent cases based on ANDA filings have regularly sought to dismiss charges of willfulness. They, like Mylan and Barr in this case, base their arguments on the *Glaxo* court's comment that "the mere filing of an ANDA cannot constitute grounds for a willful

³References to "1/27/06 Tr." are to the transcript of the January 27, 2006 teleconference in this case.

infringement determination." *Id.* at 1349. The district courts have split on the issue. See *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 444-45 (D.N.J. 2006) (collecting cases).

The more recent and growing weight of authority however, seems to be that an ANDA filing and accompanying paragraph IV certification⁴ cannot support a charge of willful infringement. See, e.g., *UCB Societe Anonyme v. Mylan Labs., Inc.*, No. 1:04-CV683-WSD, 2006 WL 486895, at *2 (N.D. Ga. Feb. 28, 2006) ("Applying *Glaxo* ..., [plaintiff's] allegations cannot support a claim of willful infringement."); *Celgene*, 412 F. Supp. 2d at 445 ("The *Glaxo* case makes clear that the Hatch-Waxman Act exists ... to permit the matter [of infringement] to be decided before the drug goes to market and an actual, rather than artificial, act of infringement occurs."); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 409 F.Supp.2d 722, 729 (E.D. Va. 2006) ("[T]he fact that the appellate court in *Glaxo* emphasizes that the purpose of the ANDA process is to create an 'artificial' act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement."). That includes recent decisions from this court. See *Item Dev. AB v. Sicor Inc.*, No. Civ. 05-336-SLR, 2006 WL 891032, at *2 (D. Del. Mar. 31, 2006) (because the filing of an ANDA and paragraph IV certification by defendant "cannot support a claim of willful infringement, plaintiffs' complaint fails to state a claim on that basis."); *Allergan, Inc. v. Alcon, Inc.*, No. 04-968, 2005 WL 3971927, at *2 (D. Del. July 25, 2005) ("As the

⁴A paragraph IV certification is a submission made with an ANDA filing, by which a generic drug manufacturer asserts that a patent on a previously FDA-approved drug is invalid or will not be infringed by the proposed generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is 'exceptional' can be based on meritless filings combined with litigation misconduct, but a finding of willful infringement cannot."⁵

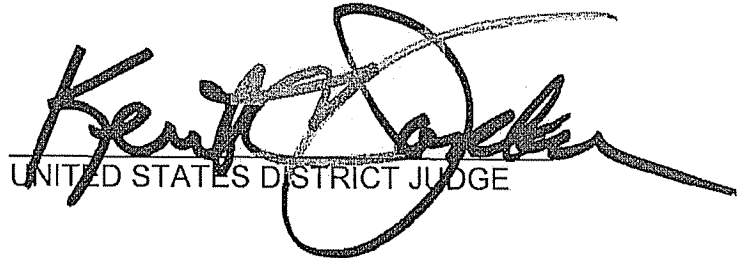
In light of that authority, which is persuasive, the plaintiffs' willfulness claims cannot stand and the motion to strike those claims will be granted. This does not, however, eliminate the question of whether there may, at some point, be occasion to find that this is an exceptional case. See *Item Dev.*, 2006 WL 891032, at *2 ("As the Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is 'exceptional' can be based on meritless filings combined with litigation misconduct, although a finding of willful infringement cannot.") (citing *Glaxo*, 376 F.3d at 1350-51); *Allergan*, 2005 WL 3971927, at *2 ("[T]he court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees."). That decision must wait, since the issue may be determined, at least in part, on the conduct of the parties during the litigation of the case. Because it may also be unnecessary to ever decide the issue, the costs associated with discovery on it should be postponed.

Conclusion

Accordingly, based on the foregoing reasons and authorities, it is hereby ORDERED that the Motion (D.I. 39), treated as a renewed Motion to Strike in which Barr joins, is hereby GRANTED to the extent described herein; it is further ORDERED

⁵I have had occasion to issue an oral ruling to that effect as well. *In re '318 Patent Infringement Lit.*, C.A. No. 05-356-KAJ (D. Del. Mar. 3, 2006) (hearing transcript at 4-7).

that all discovery associated with whether this is an "exceptional case" within the meaning of 35 U.S.C. § 285 is stayed.


UNITED STATES DISTRICT JUDGE

July 6, 2006
Wilmington, Delaware